

U.S.S.N. 10/003,983

Filed: October 31, 2001

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**Remarks in Response to Restriction Requirement**

In the Office Action mailed October 4, 2004, the claims were divided into 14 groups.

Group I, claims 1-7, drawn to a peptide comprising an HLA-binding peptide of human CD45 polypeptide or a portion or variant thereof and/or fusion protein thereof with HLA heavy chain and flexible linker;

Group II, claims 8-12, drawn to nucleic acids encoding ligand that is a peptide comprising an HLA-binding peptide of human CD45 polypeptide or a portion or variant thereof and/or fusion protein thereof with HLA heavy chain and flexible linker, vectors, transformants and expression thereof;

Group III, claims 13-18, drawn to an antigen presenting cell ("APC") loaded with a peptide and a kit comprising a peptide and an APC;

Group IV, claims 19, 21, and 23, drawn to a method for producing activated CTL *in vitro*, comprising contacting syngeneic CTL with syngeneic APC loaded with peptides;

Group V, claims 19 and 22, drawn to a method for producing activated CTL *in vitro*, comprising contacting syngeneic CTL with syngeneic APC that comprise an expression vector which expresses a peptide;

Group VI, claims 19 and 20, drawn to a method for producing activated CTL *in vitro*, comprising contacting allogeneic CTL with allogeneic APC and peptide;

Group VII, claims 24-26, drawn to activated CTL;

Group VIII, claims 27 and 28, drawn to a TCR or a functionally equivalent molecule that recognizes a malignant haematopoietic cell that expresses CD45;

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Group IX, claims 29 and 30, drawn to a polynucleotide and expression vector thereof, encoding a TCR that recognizes a cell that expresses a polypeptide comprising the amino acid sequence of claim 1 or a TCR or functional equivalent that recognizes a malignant haematopoietic cell that expresses CD45;

Group X, claims 31-34, drawn to a method of killing target cells in a patient, comprising administering activated CTL;

Group XI, claims 35-38, drawn to a method of treating a patient with a haematopoietic malignancy;

Group XII, claim 39, drawn to a library of activated CTL;

Group XIII, claim 40, drawn to a library of HLA-binding peptides of human CD45 polypeptide; and

Group XIV, claim 41, drawn to a library of APC loaded with an HLA-binding peptide of human CD 45 polypeptide.

The Examiner has additionally classified the groups of claims by species:

Group I, a specific peptide containing either only peptide bonds or including non-peptide bonds, or a specific single chain peptide/HLA molecule;

Group II, a polynucleotide/vector/host/cell method of production encoding a) a specific peptide containing either only peptide bonds or including non-peptide bonds, or b) a specific peptide and a specific HLA molecule and a specific APC;

Group III; a peptide and an APC expressing a specific MHC molecule to which the peptide binds as well as a specific species of APC;

Group IV, a species of APC expressing a specific MHC molecule to which a specific peptide binds;

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Group V, a species of APC expressing a specific MHC molecule to which a specific peptide binds, said peptide being expressed in a specific expression vector;

Group VI, a species of APC expressing a specific molecule to which a specific peptide binds;

Group VII, a species of CTL that recognize a specific MHC/peptide combination;

Group VIII, a species of TCR or a specific species of functionally equivalent molecule that recognizes a specific MHC/peptide combination;

Group IX, a species of polynucleotide that encodes a specific TCR or a specific species of functionally equivalent molecule that recognizes a specific MHC/peptide combination;

Group X, a peptide expressed on target cells on the patient, a specific species of CTL that recognizes a specific MHC/peptide combination; and

Group XI, a peptide expressed on target cells of the patient, a specific species of CTL that recognizes a specific MHC/peptide combination.

In response, applicants elected Group I, claims 1-7, and SEQ ID NO: 1 containing peptide bonds, with traverse.

The Restriction Requirement is Improper

To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect. MPEP § 806.04.

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The restriction requirement is improper because the Examiner has (1) divided single claims into a plurality of inventions and (2) refused to exam related groups together. The following are suggested groupings.

1. Groups I, II and XIII, claims 1-7, 8-12 and 40, drawn to peptides comprising an HLA-binding peptide of a human CD45 polypeptide or a portion of variant thereof, a library of such peptides and a polynucleotide encoding the peptides of Group I; an expression vector capable of expressing the peptides; a host cell containing the polynucleotide alone or in an expression vector; and a method of producing the peptide.
2. Groups III-VII, XII, and XIV, claims 13-26, 39 and 41, drawn to a kit of parts comprising a peptide of Group I and an antigen presenting cell; an antigen-presenting cell wherein its MHC Class I molecules are loaded with a peptide of Group I; a library of such cells; a method of producing activated cytotoxic T lymphocytes *in vitro* comprising contacting CTLs with antigen-presenting cell wherein its MHC Class I molecules are loaded with a peptide of Group I; activated cytotoxic T lymphocytes which recognizes a cell which expresses the polypeptides of group I; and a library of such activated CTLs.
3. Groups VIII, claims 27-28, drawn to a T cell receptor which recognizes a cell which expresses a polypeptide of group I; Group IX, claims 29-30, directed to a polynucleotide encoding a T cell receptor, and an expression vector capable of expressing a T cell receptor.
4. Groups X and XI, claims 31-38, drawn to a method of treating patients with activated cytotoxic T lymphocytes (CTL) which recognize peptides containing an HLA-binding peptide of a human CD45 polypeptide.

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Proposed Group 1, claims 1-7 are drawn to peptides containing an HLA-binding peptide of a human CD45 polypeptide and claim 40 is directed to a library of such peptides. Applicants fail to see how these two "sets" of claims are independent because the peptides are essential to both groups. Claims 8-12 are drawn to a polynucleotide encoding the peptides of Group I; an expression vector capable of expressing the peptides; a host cell containing the polynucleotide alone or in an expression vector; and a method of producing the peptide. The Examiner alleges that the groups are divergent because the nucleic acids of Groups II are distinct from the proteins of Groups I. However, in *In re Wallach*, 378 F.3d 1330, 71 USPQ2d 1939 (Fed. Cir. 2004), the Federal Circuit clearly recognized the relationship between a nucleic acid sequence and the sequence of the protein it encodes. There the court stated "it is a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it." *Id.* at 1334. Therefore once the nucleic acid sequence is known, the applicant has possession of the corresponding protein. Conversely, if the amino acid sequence is known, the applicant has possession of the nucleic acid sequence which encodes the protein. *See Id.* at 1333.

The claims of proposed Group 2 are connected in operation by the antigen-presenting cells (APCs) and the peptides of Group I. Claims 13-15 are drawn to a kit containing APCs and the peptides; claims 16-18 are directed to APCs expressing the peptides; claim 41 is drawn to a library of these APCs; claims 19-23 are directed to a method of producing activated cytotoxic T lymphocytes by contacting the CTLs with antigen-presenting cells expressing the peptides; claims 24-26 are drawn to the activated CTLs themselves; and claim 39 is directed to a library of the activated CTLs.

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The claims of proposed group 4 all relate to a method of killing target cells or treating a hematopoietic malignancy in patients by administration of activated cytotoxic T lymphocytes (CTL) which recognize peptides containing an HLA-binding peptide of a human CD45 polypeptide. Claims 31-34 and 35-38 are connected in operation (treatment with CTLs) and effect (treatment of malignant cells), and are therefore not independent.

In addition, the proposed grouping of the claims would not burden the Examiner because a divergent literature and patent search would not have to be conducted. For example, it would be very easy to search for a peptide library containing HLA-binding peptides of human CD45 polypeptide, while searching for the peptides themselves. It would also be effortless to search for APCs expressing the peptides of Group I as well as the activation of CTLs through contact with the APCs. Finally, there would be no burden on the Examiner to search for methods of treating malignancies with activated CTLs that recognize a cell which express peptides containing an HLA-binding peptide of a human CD45 polypeptide.

It is understood that where product claims are found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be fully examined.

Claim 19 is generic to three "inventions" alleged by the examiner. Claim 19 reads:

A method for producing activated cytotoxic T lymphocytes (CTL) *in vitro*, the method comprising contacting *in vitro* CTL, which antigen-loaded human class I MHC molecules expressed on the surface of a suitable antigen-presenting cell for a period of

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time sufficient to activate, in an antigen specific manner, said CTL, wherein the antigen is a peptide according to Claim 1.

The restriction requirement, by creating separate inventions out of the generic claims, makes it impossible to examine the claims in their entirety, and forces the applicants to restrict the claims to a single embodiment without any examination of the genus. Where only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary. MPEP § 808.01(a). This is clearly not the case in this application.

The Examiner argues that the species are distinct because their structures are different. However, the requirement of election of species is improperly drawn. For example, the peptide "species" are not embodiments reciting mutually exclusive characteristics as required to make a proper election of species requirement. All peptide "species" are HLA-binding peptides of the human CD45 polypeptide. In this regard applicants refer to MPEP § 806.04(f) which states in relevant part:

The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which *under the disclosure* are found in a first species but not in a second, while a second claim recites limitations *disclosed* only for the second species and not the first. (emphasis added)

Thus, this test requires that the subject matter of claims have mutually exclusive subject matter, as disclosed in the specification, for restriction to different species. Applicants note, however, that election of species should not be required if the species claimed would be considered unpatentable over each other (see MPEP § 808.01(a)). Applicants urge that this point should be carefully considered in regard to the identified

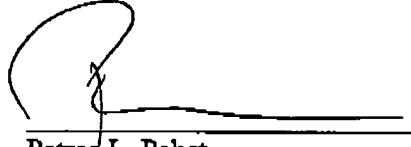
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species. Notwithstanding this, applicants note that the restriction requirement does not provide sufficient basis to indicate that examination of more than one of the "species" would overly burden the Examiner. Although it is understood that should the generic claims be found allowable, any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination, the restriction requirement is wrong and unfairly penalizes the applicants.

Favorable consideration of claims 1-41 is respectfully solicited.

Respectfully submitted,



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